64. (ADDED) The method according to claim 14, wherein said inserting the infusion cannula further includes inserting the infusion cannula operable end one of directly through the conjunctiva and sclera or through the entry aperture in each of the conjunctiva and sclera formed by the entry alignment device.

65. (ADDED) The method according to claim 18, wherein said inserting the infusion cannula further includes inserting the infusion cannula operable end one of directly through the conjunctiva and sclera or through the entry aperture in each of the conjunctiva and sclera formed by the entry alignment device.

66. (ADDED) The method of claim 26, wherein the cutting member driving mechanism is configured so as to drive the cutting member so as make at least 1500 cuts per minute past the insertion member aperture.

REMARKS

Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the foregoing amendments and the following remarks.

Claims 1-22 are pending in the subject application and claims 23-41 are withdrawn from consideration. Claims 1-13 and 15-21 stand rejected under 35 U.S.C. §102, 35 U.S.C. §103, and/or 35 U.S.C. §112, second paragraph. Claims 14 and 22 were objected to as depending from a rejected base claim, however, the Examiner indicated that these claims would be allowable if appropriately re-written in independent form.

Claim 1 was amended to correct a typo. Claims 14 and 22 were amended in the foregoing amendment so as to provide that a fluid such as a gas is infused through the infusion cannula while aspirating vitreous. Claim 17 was amended for consistency of language amongst the claims. Claim 13 was amended so as to depend from added claim 55. Claims 42-66 were added to claim embodiments of the present invention.

The specification was objected to and correction required. The drawing figures were objected to and correction required. The specification was amended to address the Examiner's objections and/or rejections. A drawing amendment is filed herewith to address certain of the drawing objections. The amendments to the specification do not introduce new matter because they either are editorial in nature or are supported by the originally filed disclosure.

Included herewith is a marked-up version of the amendments to the subject application by the current amendment. The marked-up versions are found on the pages captioned or entitled "Details of Amendments" that follow the signature page of the within Response.

35 U.S.C. §112, SECOND PARAGRAPH REJECTIONS

Claim 6 stands rejected under 35 U.S.C. 112 on the grounds that there are antecedent basis, indefiniteness and/or vagueness concerns with the identified claims. Specifically, claim 6 stands rejected as being indefinite because of the recitation "shoe-horn type of member" set forth in claim 6. Applicants respectfully traverse.

As set forth in MPEP-2173.01, a *fundamental* principle contained in 35 U.S.C. § 112, second paragraph is that applicants are their own lexicographers. Further

applicants can define in the claims what the regard as their invention essentially in whatever terms they choose so long as the terms are not used in ways that are contrary to accepted meanings in the art.

As provided in the subject application (see pg. 9, lines 6-12 thereof) the entry alignment device 100a shown in FIGS. 7A,B includes a handle portion 102, a stop portion 104 and an inserted portion 106 "*that are interconnected to each other so as to form a shoe-horn type of member.*" The discussion on page 15 of the subject application also provides that the inserted portion 106 of the entry alignment device 100a illustrated in FIGS. 7A,B includes a dished portion 107 that is configured geometrically to complement the geometric shape of the surgical instruments that can be inserted into the eye. Because the dished portion is generally configured so as to be arcuate or curved, the inserted portion 106 thus forms a troughlike blade that is inserted into the eye, penetrating the conjunctiva and the sclera and forming respective entry apertures in each. In addition, the inserted portion 106 aligns, and keeps aligned, the respective apertures formed in the conjunctiva and the sclera. This inserted portion 106 when so inserted into the eye also aids in inserting the surgical instruments into the eye. For example, the instrument can be slide along the surface of the dished portion 107 into the interior of the posterior segment of the eye thereby guiding the instrument into the vitreous.

Webster's New Universal Unabridges Dictionary, Deluxe Second Edition, provides the following as to what is a shoe-horn:

> (1) an implement made of horn, metal, etc. with a troughlike blade curved to fit the heel, inserted at the back of a shoe to aid in slipping it on,

> (2) anything by which a transaction is facilitated; anything used as a medium.

From the foregoing discussion, it is clear that the inserted portion 106 of the entry alignment device 100a illustrated in FIGS. 7A,B mimics a number of the features of a shoe-horn as well as being a device to facilitate the insertion of surgical instruments through the entry apertures formed respectively in each of the conjunctiva and the sclera. FIG. 7B, also clearly identifies the dished portion 107 of the entry alignment device inserted portion 106.

As provided in MPEP-2173.05(a), "[i]f the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is precise as the subject matter permits, the statute (35 U.S.C. 112, second paragraph) demands no more..." (citations omitted). Also, MPEP-2173.04 provides that breadth of a claim is not to be equated with indefiniteness (citations omitted). It is clear from the foregoing remarks that one skilled in the art would, upon reading claim 6 in light of the specification, understand and be apprised of the scope of the invention and its utilization.

Applicants also would note that the grounds for the rejection do not indicate that this terminology used by Applicants is not used in ways that are contrary to accepted meanings in the art of ophthalmic surgery.

Accordingly, it is respectfully submitted that claim 6 satisfies the requirements of 35 U.S.C. §112 and, as such, is in a condition for allowance.

35 U.S.C. §102 REJECTIONS

Claims 1-12 stand rejected under 35 U.S.C. § 102 as being anticipated by the cited art for the reasons provided on pages 3-5 of the above-referenced Office Action. The following addresses the specific rejections provided in the above-referenced Office Action. As indicated above claim 1 was amended to correct a typo, as such, the amendment is not considered as being made to overcome the within rejection or to distinguish the claimed invention from the cited art.

CLAIMS 1-10

Claims 1-10 stand rejected under 35 U.S.C. §102(b) as being anticipated by Skolik et al. (USP 5,817,099; "Skolik") for the reasons provided on pages 4-5 of the above referenced Office Action. Applicants respectfully traverse.

As to claim 1, it is asserted in the Office Action that Skolik discloses a method for providing access within an eye comprising providing an entry alignment device and inserting the entry alignment device into the eye. Applicants respectfully disagree with the characterization of what is being disclosed in Skolik as well as the asserted correspondence of features/ methodology disclosed in Skolik with the methodology and elements being claimed by Applicants.

As to claim 1, Applicants claim a method for providing access within an eye during an occular surgical procedure. The claimed method includes providing an entry alignment device that is configured so as to provide an entry aperture in each of the conjunctiva and sclera of the eye and maintaining the entry aperture in each of the conjunctiva and sclera aligned during the surgical procedure. The claimed method also

includes inserting the entry alignment device that is so configured into the eye *so as to form the entry apertures* namely the apertures in each of the conjunctiva and the sclera. The claimed methodology, in comparison to conventional techniques, avoids the need to dissect or pull back the conjunctiva to expose the sclera for the purposes of making an incision in the sclera through which surgical instruments and/or infusion cannulas are passed, as well as avoiding the need to make such an incision in the sclera.

As described in Gray's Anatomy the conjunctiva is a mucous membrane of the eye that lines the inner surface of the eyelids and folds so it can be reflected over the fore part of the sclerotic (i.e., sclera) and cornea. Upon the sclerotic the conjunctiva is loosely connected to the globe. Upon the cornea the conjunctiva consists only of epithelium, constituting the anterior layer of the cornea (conjunctival epithelium), however, the conjunctival epithelium is described in connection with the and as being part of the structure making up the cornea. In general, when those skilled in the art of ophthalmic surgery refer to the conjunctiva, particularly in connection with surgical procedures involving the posterior segment or globe of the eye, they are referring to the palepebral portion of the conjunctiva that extends from the periphery of the cornea backwards along the sclerotic or sclera to the eyelid.

According to the method of claim 1, there is provided an entry alignment device that is configured so as to provide an entry aperture in each of the conjunctiva and sclera of the eye when the entry alignment device is inserted into the eye. In addition the entry alignment device is configured to maintain the entry aperture in each of the conjunctiva and sclera aligned during the surgical procedure.

In contrast to the claimed invention Skolik describes a methodology whereby an incision is made in the eye sufficiently sized so as to receive the port/ seal device disclosed therein (see column 10, lines 30-48). More specifically Skolik describes the use of the disclosed port/ seal device in connection with cataract surgery, where such an incision is made in the anterior segment or globe of the eye that includes the cornea. Thus, Skolik cannot and does not disclose a methodology including a step of providing an entry alignment device *that is configured so as to provide an entry aperture in each of the conjunctiva and sclera.* This is because the method disclosed in Skolik first requires making an incision in the eye to gain access to the interior of the anterior segment and then inserting the port/seal device into the incision made in the eye. Skolik also does not disclose a technique for trans-conjunctival insertion of an entry alignment device. Also because an incision is made before insertion of the port/seal device, Skolik cannot disclose inserting the entry alignment device that is configured as claimed by Applicants into the eye *so as to form the entry apertures* as is claimed by Applicants because the incision made according to the method disclosed in Skolik forms the entry aperture.

As is also known to those skilled in the art, it is extremely difficult to make an incision in both the conjunctiva and the sclera and to thereafter have the incision in each of the conjunctiva and the sclera remain aligned. If such an incision was made in both the conjunctiva and the sclera, one would insert an instrument through the aperture in the conjunctiva and then hunt for the aperture in the sclera, basically by poking the exterior of the sclera until the instrument passed through the incision in the sclera. Such hunting or poking typically increases the risk of trauma and injury to the eye. Thus, to minimize trauma and unneeded injury to the eye, and as described in the

Background and illustrated in FIG. 1 of the subject application, the conjunctiva is typically dissected or pulled back to expose the sclera and a sclerotomy incision is then made in the sclera

Moreover, as discussed more fully below in connection with claims 2 and 3, an incision of the size needed to insert the port/seal device disclosed in Skolik if made in the sclera would not be seal-sealing but rather would require suturing or some other means for closing or sealing the incision. Again, and as known to those skilled in the art, to allow for such closing of the incision by suturing, the conjunctiva would be dissected or pulled back to expose the sclera.

Applicants also would note that Skolik is completely silent as to the techniques for making the incision in the eye as Skolik merely provides that the incision has already been made before the port/ seal device disclosed therein is inserted.

As to claims 2-3, the Office Actions asserts that Skolik discloses that after the device is removed the entry apertures are self-sealing. It would appear that the Office Action is based on the assumption that the self-healing assertions made in Skolik in connection with cataract surgery in the anterior segment apply equally to incisions made in the eye in general for any ocular surgical procedure. As is known to those skilled in the art such a broad assumption is incorrect, particularly for incisions in the sclera in the posterior segment.

The tissues making up the anterior segment of the eye have different mechanical properties that those for the sclera in the posterior segment. As is known to those skilled in the art, the stepped type of incision described in column 2, lines 32-39 of Skolik referred to by the Examiner is support of the rejection of these claims does not

work for vitroretinal surgical procedures and would not leave an incision that would be self sealing in the sclera.

Skolik also provides that the outer surface of the body 2 will have a maximum diameter of 3.0 to 6.0 mm (see col. 8, lines 14-17). As is known to those skilled in the art, the incision required to allow a body of such a diameter to be inserted into the sclera would not be self sealing and would have to be closed by suturing or other techniques.

As to claims 4 and 5, it is asserted that Skolik discloses proving and inserting an instrument having a operable end that is less than 25 gauge with reference to col. 1, lines 41-43. These lines provide that the instrument has an outside diameter of about 1mm. As indicated in the subject application at page 2 thereof 19-20 gauge corresponds to a diameter of approximately 1mm. Also, and as is known to those skilled in the art, 25 gauge corresponds to a diameter of about 0.5 mm. Thus, the cited language in Skoilk does not disclose explicitly or inherently providing and inserting an instrument having an operable end of less than 25 gauge.

In sum, Skolik does not disclose, suggest nor teach the methodology of the present invention as set forth in any of claims 1-10.

It is respectfully submitted that claims 1-10 are patentable over Skolik for the foregoing reasons.

CLAIMS 1, 11 & 12

Claims 1 and 11-12 stand rejected under 35 U.S.C. 102(e) as being anticipated by Covard (USP 5,676,669 for the reasons provided on page 5 of the above referenced Office Action. Applicants respectfully traverse.

More particularly, the Office Action asserts that Colvard discloses a method for providing access within an eye comprising providing an entry alignment device and inserting the entry alignment device at an angle less than 45 degrees with respect to a normal. Specific reference is made to the discussion in column 8, lines 5-13, figure 8A and the cylindrical insertion device 34. Applicants respectfully disagree with this characterization of what is disclosed in Colvard as well as the asserted correspondence of features/ methodology disclosed in Colvard with the methodology and elements being claimed by Applicants.

Colvard, much like Skolik, describes a cataract surgical procedure in which an incision is made in the anterior segment or globe of the eye. In contrast to the present invention, there is no entry alignment device disclosed in Colvard and the use of an entry alignment device is not referred to in the procedure described in Colvard. As described throughout Colvard the surgical instruments being used in the cataract surgical procedure are inserted through the incision 28 made in the anterior segment of the eye and the hole 30 made in the anterior portion of the eye's lens capsule 22. Thus, Colvard does not and cannot disclose any of the method steps of claim 1.

As to the suggestion that the cylindrical insertion device 34 some how comprises an entry alignment device, Applicants respectfully submit that such an assertion is not supported by the disclosures in Colvard. As described in Colvard, a capsular shield 10

is disposed within the cylindrical insertion device 34 and the cylindrical insertion device is inserted into the eye through the incision 28 so that the shield can be deployed from the cylindrical insertion device within the lens capsule. As also described in Colvard, the cylindrical insertion device 34 can be used to recover the capsular shield therein after the shield's use in the procedure is complete so the shield can be removed from within the eye's anterior segment. In other words, the cylindrical insertion device 34 is nothing more than another surgical instrument that is inserted into the eye's anterior segment. Thus, the cylindrical insertion device 34 is not nor corresponds to an entry alignment device as that term is used in the present invention. Moreover, the cylindrical insertion device 34 described in Colvard is not configured to provide an entry aperture in each of the conjunctiva and the sclera nor to be inserted into the eye to form these entry apertures.

As to claims 11 and 12, the figures in Colvard do not illustrate inserting an entry alignment device into the eye so as to make entry apertures in the conjunctiva and the sclera at an angle with respect to the normal of the eye.

It is respectfully submitted that claims 1 and 11-12 are patentable over the cited reference for the foregoing reasons.

The following additional remarks shall apply to each of the above.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suziki Motor Co.*, 868 F.2d

1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). It is clear from the foregoing remarks that claims 1-10 are not anticipated by Skolik and that claims 1 and 11-12 are not anticipated by Colvard.

As the Federal Circuit has indicated, in deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify *corresponding elements* disclosed in the allegedly anticipating reference (emphasis added, citations in support omitted). *Lindemann Maschinenfabrik GMBM v. American Hoist and Derrick Company et al.*, 730 F. 2d 1452, 221 USPQ 481,485 (Fed. Cir. 1984). In concluding that the `770 Patent did not anticipate the claims, the Federal Circuit in *Lindemann Maschinenfabrik GMBM v. American Hoist and Derrick Company et al.*, at 221 USPQ 485-486, further provides that:

> The `770 patent discloses an entirely different device, composed of parts distinct from those of the claimed invention, and operating in a different way to process different materials differently. Thus, there is no possible question of anticipation by equivalents. Citations omitted.

It is clear from the foregoing remarks, that the entry alignment devices allegedly disclosed in either Skolik and Colvard do not in fact correspond to the entry alignment devices as set forth in any of the claims of the present invention. As also indicated above, the method disclosed and taught in either Skolik or Colvard describes surgical procedures in which an incision is made in the anterior segment of the eye and that

does not involve a transconjunctival insertion of the entry alignment device so as to form entry apertures in each of the conjunctiva and the sclera. In sum, the disclosures of both Skolik and Colvard are completely different from that claimed and taught by Applicants. Thus, there can be no explicit or inherent disclosure or teaching in either Skolik or Colvard of Applicants' invention.

It is respectfully submitted that for the foregoing reasons, claims 1-12 are patentable over either of Skolik or Colvard two cited reference(s) and thus satisfy the requirements of 35 U.S.C. §102. As such, these claims, including the claims dependent therefrom are allowable.

35 U.S.C. §103 REJECTIONS

Claims 13 and 15-22 stand rejected under 35 U.S.C. §103 as being unpatentable over Petman [USP 5,487,725] in view of Skolik and Saperstein {USP5,919,158]. Applicants respectfully traverse.

The Office Action asserts that Peyman discloses the invention as claimed except for the use of the entry alignment devices and the insertion of a light source. It also is asserted that Skolik discloses that an entry alignment device should be used for ocular surgery and that Saperstein teaches the use of a light source to illuminate the area the surgeon is working on. Applicants respectfully disagree at least with the characterization of what is disclosed in Peyman and Skolik as well as the asserted correspondence of features/ methodology disclosed in Peyman and Skolik with the methodology and elements being claimed by Applicants. Although used for a limited

purpose, Applicants also submit that Saperstein does not cure the shortcomings of the other two cited references.

Peyman disclose the known technique of making a sclerotomy incision (i.e., an incision in the sclera) and inserting a probe through the sclerotomy incision into the vitreous cavity. As is known to those skilled in the art, to make this incision in the sclera the conjunctiva is first dissected or pulled back to expose the sclera. It also might be possible to make a large incision in the conjunctiva so as to expose the sclera sufficiently to make the required sclerotomy incision. Thus, Peyman does not disclose, suggest or teach, explicitly or inherently, the transconjunctival methodology claimed by Applicants.

As indicated in the discussion above regarding the §102 rejection of claim 1 as being anticipated by Skolik, Skolik does not disclose providing an entry alignment device that is configured to form entry apertures in each of the conjunctiva and the sclera of the eye when the device is inserted into the eye. Skolik also fails to disclose inserting such an alignment device into the eye so as to form such entry apertures. As also indicated therein, Skolik discloses making an incision in the eye prior to inserting a portion of the port/ seal device disclosed in Skolik through the incision. It thus is further asserted that Skolik nowhere teaches, suggest or offers any motivation for providing an entry alignment device as claimed by Applicants or a methodology for inserting such an entry alignment device into the conjunctiva and the sclera so as to form the respective entry apertures.

Saperstein is used for the limited purpose of teaching the use of a light source to illuminate an area. Saperstein, however, also describes the known technique of

inserting surgical instruments/ cannulas/ light probe through a sclerotomy (i.e., sclerotomy incision) in the eye. Thus, Saperstein does not disclose, teach or suggest the transconjunctival methodology claimed by Applicants.

It is respectfully submitted that the cited references, alone or in combination, do not disclose, teach or suggest providing an entry alignment device configured to form entry apertures in each of the conjunctiva and the sclera when the device is inserted into the eye nor maintaining such apertures in the conjunctiva an sclera aligned during the surgical procedure. Ii also is respectfully submitted that the cited references, alone or in combination, do not disclose, teach or suggest the transconjunctival methodology or technique of the present invention. Further, the cited references, alone or in combination do not disclose, teach or suggest performing a retinal detachment procedure wherein a plurality of entry alignment devices as claimed by Applicants are provided and inserted into and through each of the conjunctiva and the sclera and to make each of the entry apertures in the conjunctiva and the sclera and to keep these entry apertures aligned during the surgical procedure.

In sum, each of the cited references describes a methodology in which an incision is made in the eye prior to insertion of the surgical instruments (Peyman and Saperstein) or the port/ seal device of Skolik. As is known to those skilled in the art, making an incision in the sclera of the posterior segment involves the dissection or pulling back of the conjunctiva prior to expose the sclera. Thus, none of the cited references can explicitly or inherently disclose the method for treating a posterior segment of an eye in which both the conjunctiva and the sclera are traversed by the entry alignment device.

Assuming, arguendo, that Peyman, Skolik and Saperstein teach what is suggested in the Office Action, Applicants assert that the 35 U.S.C. § 103 rejection of the claims is still improper because the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). In order to make out a prima facie case of obviousness, there must exist in the cited references some suggestion or teaching to combine the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat App. & Inter. 1993). Moreover, the references must contain an indication that the resultant combination will be reasonably successful.

As provided in the foregoing remarks, the three cited references do not teach or suggest the features of the provided entry alignment device claimed by Applicant. Further, the three cited references do not teach or suggest the combination of steps of the method claimed by Applicants. In addition, there is no suggestion anywhere in these references that such a combination would be reasonably successful.

The Federal Circuit has indicated in connection with 35 U.S.C. §102 that in deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify *corresponding elements* disclosed in the allegedly anticipating reference (emphasis added, citations in support omitted). *Lindemann Maschinenfabrik GMBM v. American Hoist and Derrick Company et al.*, 730 F. 2d 1452, 221 USPQ 481,485 (Fed. Cir. 1984). Notwithstanding that the instant rejection is under 35 U.S.C. §103, in the present case the Examiner has not shown that the devices and method steps in any of

the three cited references corresponds, as that term is used above by the Federal Circuit, in any fashion to the provided entry alignment devices and methodology in their entire claimed form as set forth in any of claims 13 and 15-22 of the present invention.

As provided in MPEP 2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F. 2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F. 2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). As provided above, the references cited, alone or in combination, include no such teaching, suggestion or motivation. As also noted above, some of the insertions are in fact inconsistent with the knowledge of those skilled in the art.

It is respectfully submitted that for the foregoing reasons, claims 13 and 15-22 re patentable over the cited reference(s) and satisfy the requirements of 35 U.S.C. §103. As such, these claims, including the claims dependent therefrom are allowable.

CLAIMS 14 & 22

As indicated above, claims 14 and 22 were objected to as depending from a rejected base and that these claims would be allowable if appropriately re-written in independent form.

In as much as Applicants believe that the base claim, claim 55, is allowable and/ or the intervening claim 13-14 also is separately allowable Applicants have not re-written claims 14 and 22 as suggested by the Examiner. Applicants, however, reserve

the right to later amend any claims 14 and 22 so as to be in independent form or to add one or more independent claims including the limitations of any of claims 14 and 22.

CLAIMS 42-66

As indicated above, claims 42-66 were added to more claim embodiments of the present invention. These added claims are clearly supported by the originally filed disclosure, including the originally filed claims. It also is respectfully submitted that these added claims are patentable over the cited prior art on which the above-described rejection(s) are based.

SEPCIFICATION OBJECTIONS

The Examiner objected to the specification of the subject application and requested correction thereof for the reasons provided on page 2 of the above-referenced Office Action. The following addresses the specific objections of the Examiner.

Applicants amended the paragraph on page 25 as suggested by the Examiner. In addition and as discussed below in connection with the objections to the drawing figures, Applicants have further amended the specification to correct a typo occurring on page 30.

The foregoing amendments do not introduce new matter, as they are editorial in nature. Thus, entry of these amendments into the subject application is respectfully requested.

It is respectfully submitted that for the foregoing reasons, the specification satisfies applicable Patent laws and rules and, therefore is considered acceptable.

DRAWING OBJECTIONS

The Examiner objected to the drawing figures for the reasons set forth on pages 2-3 of the above referenced Office Action and requested correction of same. An amendment to the drawing is being submitted herewith as described below to address the Examiner's objections. As such the drawing, as amended, is considered acceptable.

As to FIG. 1 and FIG. 8, these drawing figures are being amended as suggested by the Examiner. An amended drawing figure for each of FIG. 1 and FIG. 8 is enclosed herewith.

The above-referenced Office Action indicates that the drawing figures are unacceptable because they do not include either reference sign 202 or 202a mentioned in the description. Applicants presume that the Examiner is referring to the last paragraph on page 29 and the first paragraph on page 30 as to the source of the reference numerals mentioned in the description. Applicants also would note that reference numeral 202 is found in FIG. 20A.

Upon reading these two paragraphs on pages 29 and 30 in conjunction with FIG. 20A, as well the paragraphs that follow on pages 30-31 concerning FIG. 20B, it is clear that reference numeral 202 on page 30, line 6 should have been 202a so as to be consistent with the discussion on page 29 and that reference numeral 202 on FIG. 20A also should have been 202a to be consistent with the discussion on page 29. Accordingly, Applicants have amended the specification (i.e., page 30) in the foregoing amendment and are submitting a drawing amendment to amend FIG. 20A in the described manner.

The Office Action indicates that FIGS. 7A,B are objectionable because the specification describes that the device in these figures "should be shaped as a 'shoe-horn type of member' but the device shown in these figures does not look like a shoe-horn type of member." Applicants refer the Examiner to the clarification offered above regarding the rejection of claim 6 under §112, second paragraph. In view of this clarification, Applicants do not believe that further amendment of FIGS. 7A-B is required to address this objection.

Applicants thus consider the drawing figures to be in acceptable form in view of the amendments thereto, the amendment to the specification and the foregoing clarification.

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Because the total number of claims and/or the total number of independent claims in the subject application post amendment now exceeds the highest number previously paid for, a check is enclosed herewith for the required additional fees. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for

any excess fee paid, the Commissioner is hereby authorized and requested to charge

Deposit Account No. **04-1105**.

Respectfully submitted,
EDWARDS & ANGELL, LLP
DBRC Intellectual Property Practice Group

Date: December 17, 2002

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DETAILS OF AMENDMENTS

Please amend the subject application as follows:

IN THE SPECIFICATION

Page 25, rewrite paragraph starting at line 14 to read as follows:

The moveable member 504 includes a device grasping portion 506 and is pivotably disposed within the handle member 502 so that the device grasping portion 506 can be selectively moved between a grasping position and a mounting position. In the mounting position, as more clearly shown in FIG. 14, the moveable member 504 is depressed into the handle member 504 so as to cause the device grasping portion 506~~505~~ to move away from the stylet 508 thus preparing the insertion tool 500 so an entry alignment device can be mounted thereon. Thereafter the movable member 504 is released thereby preferably causing the device grasping portion to move towards the stylet 508~~505~~ thereby grasping the device and removably securing the entry alignment device to the insertion tool 500 as more clearly shown in FIG 15.

Page 30, rewrite paragraph starting at line 1 to read as follows:

The stop portion 204 is configured and arranged so as to provide a sufficient surface area and thickness to prevent the infusion cannula 200a from being drawn or drifting into the intra-ocular volume of the eye. The stop portion 204 and the inserted portion 206 are configured so as to include in each a lumen that communicates with each other and the lumen in the nozzle portion 202a. In this way, the fluid from the infusion source flows through the successive lumens and into the intra-ocular volume of the eye.

IN THE CLAIMS

Cancel claim(s) 23-41 without prejudice.

Amend claims 1, 13-14, 17, and 22 to read as follows:

1. (AMENDED) A method for providing access within an eye during an occular surgical procedure, comprising the steps of:

providing an entry alignment device that is configured so as to provide an entry aperture in each of the conjunctiva and sclera of the eye and maintaining the entry aperture in each of the conjunctiva and sclera aligned during the surgical procedure; and

inserting the entry alignment device into the eye so as to form the entry apertures.

13. (AMENDED) The method of claim 55 wherein said step of implementing further includes ~~A method for treating a posterior segment of an eye comprising the steps of:~~

~~providing a plurality of entry alignment devices that is configured so as to provide an entry aperture in each of the conjunctiva and sclera of the eye and maintaining the entry aperture in each of the conjunctiva and sclera aligned during the surgical procedure;~~

~~inserting each of the plurality of entry alignment devices into the eye;~~

inserting a light source through the entry aperture formed by one of the plurality of entry alignment devices and inserting a high speed vitreous cutting/ aspirating instrument in the entry aperture formed by another of the plurality of entry alignment devices; and

removing vitreous gel using the high speed vitreous cutting/ aspirating instrument.~~; and~~

~~implementing a corrective procedure for the retina.~~

14. (AMENDED) The method of claim 13, further comprising the steps of:

inserting an operable portion of an infusion cannula through the conjunctiva and the sclera; and

maintaining the intraocular volume by infusing a fluid through the infusion cannula;

infusing a first fluid ~~gas~~ through the infusion cannula while aspirating vitreous fluid; and

exchanging the infused first fluid ~~gas~~ with a second fluid ~~gas~~ following the step of implementing.

17. (AMENDED) The method according to claim 15, wherein the entry alignment device is in the form of one of a metal cannula, a polyimide cannula, a wire spreader and a shoe-horn type ~~chisel point~~ member.

22. (AMENDED) The method of claim 14, further comprising the steps of:

infusing a first fluid ~~gas~~ through the infusion cannula while aspirating vitreous fluid; and

exchanging the infused first fluid ~~gas~~ with a second fluid ~~gas~~ following the step of implementing.

Add new claim(s) 42-66 that read as follows:

42. (ADDED) A method for providing access within an eye during an ocular surgical procedure, comprising the steps of:

providing an insertion tool having a penetrating member and an entry alignment device;

removably mounting the entry alignment device onto the insertion tool penetrating member; and

inserting the penetrating member into the eye, so the penetrating member and a portion of the entry alignment device penetrate each of the conjunctiva and sclera of the eye, whereby said portion of the entry alignment device establishes an entry aperture in each of the conjunctiva and sclera of the eye and maintains the entry aperture in each of the conjunctiva and sclera aligned during the surgical procedure.

43. (ADDED) The method according to claim 42, further includes the steps of:

removing the penetrating member from the eye; and

maintaining the portion of the entry alignment device disposed in the eye.

44. (ADDED) The method according to claim 42, wherein the entry alignment device is configured so as to include a through aperture and wherein said method further includes the steps of:

removing the penetrating member from the eye; and

maintaining the portion of the entry alignment device disposed in the eye, whereby the entry alignment device through aperture forms a passage extending between an interior and an exterior of the eye.

45 (ADDED) The method according to claim 44, wherein the entry alignment device being provided is sized such that when said portion of the entry alignment device is removed from the eye, the entry aperture formed in the conjunctiva and sclera are sealed without the use of sutures.

46. (ADDED) The method according to claim 45, wherein the entry alignment device being provided is sized such that when the entry alignment device is removed from the eye, the entry aperture is self sealing.

47. (ADDED) The method according to claim 44, further comprising the steps of:

providing a surgical instrument having an operable end for insertion through the entry alignment device through aperture, a portion of the operable end having a cross-sectional diameter not greater than 25 gauge; and

inserting the surgical instrument through the entry alignment device through aperture into the eye.

48. (ADDED) The method according to claim 47, wherein the surgical instrument is selected from the group consisting of a high-speed vitreous cutter, forceps, scissors, pick, light source, laser, fragmentation, diathermy, and aspirator.

49. (ADDED) The method according to claim 44, wherein the entry alignment device is in the form of one of a metal cannula or a polyimide cannula.

50. The method according to claim 44, wherein said step of inserting includes inserting the penetrating member and said portion of the entry alignment device into the eye so the entry apertures in the conjunctiva and sclera are at an angle with respect to a normal to the eye.

51. (ADDED) The method of claim 44, wherein the insertion tool being provided includes a handle member, where the penetrating member extends from an end of the handle member.

52. (ADDED) The method of claim 51, wherein the insertion tool further includes a mechanism for removably securing the entry alignment device to the insertion tool.

53. (ADDED) A method for treating a posterior segment of an eye comprising the steps of:

providing an insertion tool having a penetrating member and a plurality of entry alignment devices, each entry alignment device having a through aperture;

removably mounting one of the plurality of entry alignment devices onto the insertion tool penetrating member;

inserting the penetrating member into the eye, so the penetrating member and a portion of said one of the plurality of entry alignment devices penetrate each of the conjunctiva and sclera of the eye, whereby said entry alignment device portion establishes an entry aperture in each of the conjunctiva and sclera of the eye and

maintains the entry aperture in each of the conjunctiva and sclera aligned during the surgical procedure;

removing the penetrating member from the eye, whereby the entry alignment device through aperture of said one of the plurality of entry alignment devices forms a passage extending between an interior and an exterior of the eye; and

repeating said steps of removably mounting, inserting and removing for each of the plurality of entry alignment devices; and

implementing a corrective procedure for the retina.

54. (ADDED) The method of claim 53, wherein said step of implementing a corrective procedure further includes:

inserting a light source through the entry alignment device through aperture of one of the plurality of entry alignment devices;

inserting a high speed vitreous cutting/ aspirating instrument through the entry alignment device through aperture of another of the plurality of entry alignment devices; and

removing vitreous gel using the high speed vitreous cutting/ aspirating instrument.

55. (ADDED) A method for treating a posterior segment of an eye comprising the steps of:

providing a plurality of entry alignment devices, each entry alignment device being configured so as to provide an entry aperture in each of the conjunctiva and sclera of the eye and maintaining the entry aperture in each of the conjunctiva and sclera aligned during the surgical procedure;

inserting each of the plurality of entry alignment devices into the eye; and

implementing a corrective procedure for the retina.

56. (ADDED) A device kit including:

an insertion tool including a penetrating member;

at least one entry alignment device that is configured so as to be removably mounted to the insertion tool penetrating member and so a portion of the at least one entry alignment devices provides an entry aperture in each of the conjunctiva and sclera of the eye and to maintain the entry aperture formed in each of the conjunctiva and sclera aligned during a surgical procedure.

57. (ADDED) The device kit of claim 56, wherein the alignment device is sized such that when the entry alignment device is removed from the eye, the entry aperture formed in the sclera is one of self-sealing sealed or without the use of sutures.

58. (ADDED) The device kit of claim 56, wherein the entry alignment device ic configured so as to include a through aperture that is sized to received therein surgical instruments having a cross-sectional diameter of not more than 25 gauge.

59. (ADDED) The method of claim 56, wherein the insertion tool being provided includes a handle member, where the penetrating member extends from an end of the handle member.

60. (ADDED) The method of claim 56, wherein the insertion tool further includes a mechanism for removably securing the entry alignment device to the insertion tool.

61. (ADDED) The device kit of claim 56, further comprising a plurality of entry alignment devices and a plurality of penetrating members, one penetrating member for each of the plurality of entry alignment devices.

62. (ADDED) The device kit of claim 56, further comprising a plurality of entry alignment devices and a plurality of penetrating members, wherein each of the plurality of entry alignment devices is mounted upon a respective one of the plurality of penetrating members.

63. (ADDED) The method according to claim 9, wherein said inserting the infusion cannula further includes inserting the infusion cannula operable end one of directly through the conjunctiva and sclera or through the entry aperture in each of the conjunctiva and sclera formed by the entry alignment device.

64. (ADDED) The method according to claim 14, wherein said inserting the infusion cannula further includes inserting the infusion cannula operable end one of directly through the conjunctiva and sclera or through the entry aperture in each of the conjunctiva and sclera formed by the entry alignment device.

65. (ADDED) The method according to claim 18, wherein said inserting the infusion cannula further includes inserting the infusion cannula operable end one of directly through the conjunctiva and sclera or through the entry aperture in each of the conjunctiva and sclera formed by the entry alignment device.

66. (ADDED) The method of claim 26, wherein the cutting member driving mechanism is configured so as to drive the cutting member so as make at least 1500 cuts per minute past the insertion member aperture.